

### Remarks/Arguments

#### Re: 103 Rejections

Applicant respectfully asks Examiner to reconsider the following arguments and to allow the claims 1-4, 17 and 18.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (MPEP, *supra* note 39, at § 2142) and (In re Vaeck, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

According to MPEP-2141, in consideration and determination of obviousness under 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) Claimed invention must be considered as a whole;
- (B) References must be considered as a whole (and they must suggest the desirability, and thus obviousness, of making the proposed combination);
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

#### **The proposed combination of references does not teach or suggest all elements**

The specific references cited ("Polymorphism in Molecular Crystals", Joel Bernstein, Oxford University Press Inc., New York (2002), pages 253-254 and US5,614,560) fails to teach or suggest all claim limitations. For instance, the Joel's reference does not specifically teach or suggest any elements for existence, preparation and characterization of amorphous form of memantine hydrochloride or amorphous

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memantine hydrochloride with less than 10% crystalline material of the claimed invention. The specific reference cited (US5,614,560) doesn't actually teach or suggest, on its face, the new subject matter being patented (e.g., doesn't actually teach or suggest amorphous form of memantine hydrochloride and pharmaceutical composition comprising it). The reference US5, 614,560 merely teaches a method of using memantine or its salts for therapeutic treatments. The proposed combination of both references cited does not specifically teach or suggest all elements of the claimed invention. The record does not appear to establish the requisite motivation for combining Joel's reference and reference US 5,61560.

### **Reference Teaches Away**

In addition, the specific reference cited ("Polymorphism in Molecular Crystals", Joel Bernstein, Oxford University Press Inc., New York (2002 pages 253-254) teaches away the claimed invention. On page 253, Joel's reference states "Because of their metastable state, amorphous materials are often difficult to prepare and handle, there is always the possibility that a stable crystalline state will crystallize from the amorphous material, leading to changes in properties and possibly rendering the resulting form unsuitable for pharmaceutical use...". Thus this prior art teaches or suggests that the claimed invention would not work.

### **Change the Principle of Operation**

The proposed combination of Joel's reference and reference US5,614,560 is improper and contrary to the precepts of MPEP §2143.01 which requires that the proposed modification cannot change the principle of operation of a reference. Reference 5,614,560 teaches merely a method of a compound for therapeutic treatments, and it is principally not relevant to polymorphism (e.g., amorphous form) of a compound.

Therefore by using each individual reference cited or combination of known elements in both references, the Examiner hasn't met the burden of proving obviousness of the claimed invention.

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In summary, the subject matter of claimed invention is non-obviousness, and claims 1-4, 17 and 18 are patentable over references cited. Therefore, applicant respectfully asks Examiner to reconsider claims 1-4, 17 and 18.

**Re: Allowable Subject Matter**

Examiner has agreed that the methods or processes for making the amorphous form of memantine hydrochloride are allowable subject matter. Applicant amended claims 5 and added a new claim 20, by including specific procedures, conditions or parameters. As a result of amendments and rewritten as suggested by Examiner, claims 6-7 and 10-12 are now withdrawn. Thus, independent claims 5, 20 and their dependent claims 8-9 and 13-16 are allowable subject matter.

Applicant respectfully asks Examiner to give applicant another non final office action since it is premature to issue Final Office Action just after first non final office action.

Respectfully submitted,  
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**Statement of no new matter added in substitute specifications**

Sir:

In response to the Office communication concerning "Office Action Summary on March 14, 2006, the applicant corrected the non-compliant in non-final amendment (8/24/05). There is no new matter added in this amendment.

Respectfully submitted,  
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**Amendments to the Drawings:**

Formula I was the chemical structure of memantine hydrochloride, which is now directly inserted the page of the substitute specification (refer to Amendments to the Specification, the substitute specification of marked up or clean copies, submitted on Date August 24, 2005).

The drawing for Figure 1 is resubmitted this time, labeled as "Replacement Sheet". The caption of Figure 1 is not amended this time.

Figure 2 was for Formula I (chemical structure of memantine hydrochloride), which is now not needed (or cancelled), as the chemical structure is directly inserted into the page 1 of specification.